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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,575	07/30/2003	Lawrence M. Tsal	CV0323 NP	8662

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EXAMINER
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REICHLER, KARIN M

ART UNIT	PAPER NUMBER
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3761

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/01/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/630,575

Applicant(s)

TSAL ET AL.

Examiner

Karin M. Reichle

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,11-13,17,23 and 24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,11-13,17,23 and 24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 4/06 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Amendment***

1. The following action is based on the Figures filed 4/06, the abstract filed 4/06 and 11/06, the claims filed 11/06, the remarks filed 4/06 and 11/06 and the amendments to the specification filed 11/06.

### ***Specification***

2. The drawings were received on 4/06. These drawings are approved.

### ***Description***

3. The disclosure is objected to because of the following informalities: In the amendments to pages 8, 15 and 16, the brackets added by the 11/06 amendment, i.e. shown underlined, should be deleted. Appropriate correction is required.

### ***Claim Objections***

4. Claims 12-13, 17 and 23-24 are objected to because of the following informalities: In claim 12, line 2, "(i)...pouch, and (ii)" is redundant, see amendments to claim 1. In claim 23, last two lines, "a(second)...track" should be --the curvature of the path along the track--. In claim 24, the second to last line, "of the slider" should be deleted. Appropriate correction is required.

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5. Applicant is advised that should claim 1 be found allowable, claim 13 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

See the second to last sentence of claim 1 and line 5 of claim 1.

### ***Claim Rejections - 35 USC § 112***

6. Claims 1, 11-13, 17 and 23-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, a clear positive antecedent basis for "the reclosable opening" on the third to last line should be set forth, i.e. "the...opening ...on the curved...length to permit" could be -- said part of the curved periphery opened by said fastener having a length which permits". In claim 23, a positive structural antecedent basis for "the path" should be defined.

### ***Claim Language Interpretation***

7. The terminology "periphery" as defined by the dictionary is "the external boundary or surface of a body". The terminology "along" is defined by the dictionary as "in a line parallel with the length or direction of". The terminology "facilitate" is defined by the dictionary as "to make easier". It is noted that the terminology "to make easier" is considered relative.

***Claim Rejections - 35 USC § 103***

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 1, 11-13, 17 and 23-24 are rejected under 35 U.S.C. 103 as being unpatentable over Sato et al , '695, in view of Hulett '553 and Morton '241.

Claim 1: See Figures 1a-1d and note the curved periphery of the outer pouch in cross-section and col. 4, line 61-col. 5, line 25, col. 6, line 55-col. 7, line 61 and col. 1, lines 12-27 of Sato, i.e. Sato teaches an ostomy pouch, see Figures and col. 7, lines 28-34, for receiving human body waste from a stoma having inner and outer pouches, 15 and 10, the outer pouch includes a curved periphery, see Figures 1b-1d, i.e. walls are curved from bottom of pouch to adjacent the mouth, and a fastener 14 on the outer pouch configured to permit re-closeable opening of the outer pouch "along" part of the curved periphery, see Figure 1a or Figures 1b-1d, i.e. 14 extends in a line parallel with the length or direction of at least a part of the curved periphery, e.g. the edge of the curved wall 10 adjacent 14 in the Figures 1b-1d directed into the page or the lower of the two solid lines at the top of Figure 1a (It is noted that the claim does not require the fastener travel along a curved path which path defines a curved portion of the periphery which also defines the opening) for replacement of the inner pouch, see the following discussion. The outer pouch is attachable to the body and includes a first aperture for accommodating a stoma, and the inner pouch includes a second aperture at least partly aligned for communication with the first aperture when said inner and outer pouches are in an operative position, the inner pouch being removably securable directly or indirectly to the outer pouch by a separable coupling, see Figures 1a-1d and col. 6, line 55-col. 7, line 27. The separable coupling permits replacement of

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the inner pouch by a replacement inner pouch, see col. 7, lines 28-61. Applicant now claims 1) the fastener for reclosable opening of a pouch being a sliding zipper fastener and 2) the recloseable opening on the curved periphery being adequate in length to permit folding of an outer pouch wall so as to "facilitate" access to the separable coupling. With respect to 1) while Sato et al teaches a pouch having a fastener, it does not teach such fastener being a sliding zipper fastener. Note however claim 6 and col. 10, lines 15-18 thereof. Further more see Hulett '553 at the Figures and col. 2, lines 6-23 and 36-40 and col. 3, line 30-35 as well as Morton '241 at Figures 5-6B, the title and col. 6, line 38-col. 7, line 13, i.e. '241 teaches interchangeability of openable/closable ostomy pouch mouth with openable/closable ostomy pouch mouth with a slider 31 and a track, i.e. the portion of the outer portion of the mouth complementary to structure 32. Therefore, to make the pouch reclosable opening fastener of Sato a pouch reclosable opening fastener as taught by Hulett and Morton instead, i.e. of the sliding zipper type, would either be obvious, see *In re Siebentritt*, 54 CCPA 1083, i.e. two equivalents are interchangeable for their desired function, express suggestion of desirability of substitution not needed to render such substitution obvious, or obvious in view of the interchangability as taught by Morton. Note also the discussion of claims 23-24 infra. With regard to 2), it is the Examiner's first position that the length of the periphery opened is adequate in length to permit folding, i.e. the mouth when opened is rounded/folded, so as to "facilitate", see the Claim Language Interpretation section supra, access to the separable coupling, see Figure 1d and compare size of mouth to that of Figure 1c. In any case, i.e. the Examiner's second position, note also Figure 6B as compared to Figure 6A of '241, i.e. rounding/folding of mouth. Therefore, the prior art combination necessarily and inevitably teaches the length of the

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periphery opened is adequate in length to permit folding, i.e. curving, so as to “facilitate” access to the coupling. It is further noted that an opening of any length would “make it easier” than no opening to access the coupling.

Claim 11: See col. 6, line 55-col. 7, line 61. It is noted that the portion of the coupling which is adhesive has not been specifically claimed.

Claim 12: See discussion of claim 1 and col. 7, lines 54-56 of Sato again.

Claim 13: See discussion of claim 1 and col. 4, lines 61-63 of Sato again.

Claim 17: See col. 5, lines 11-17 and col. 7, lines 54-56 of Sato.

Claim 23: The sliding zipper fastener of ‘241 includes at least one zipper track and a movable slider, i.e. the portion of the outside of the pouch opposite 32 and 31, respectively, and the slider includes one or more track engaging surfaces 32 having a characteristic to accommodate a curvature of the path of the slider along the track, i.e. the curvature of the portion opposite 32 in Figure 5.

Claim 24: See the discussion of claim 23 and note the track/portion opposite 32 is not toothed.

### ***Response to Arguments***

10. Applicant’s remarks have been considered but are either deemed moot in that the issue discussed has not been repeated or not persuasive for the reasons set forth supra. It is noted that the combination of Sato and Hulett was not discussed, i.e. such references were discussed only singly. It is again noted that the claims do not require a curved zippered opening.

*Conclusion*

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not applied art also teaches ostomy pouches or medical use pouches with fastening features.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any new grounds of rejection were necessitated by the amendments to claims 1, 11-13, 17 and 23-24.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karin M. Reichle whose telephone number is (571) 272-4936. The examiner can normally be reached on Monday-Thursday.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Karin M. Reichle  
Primary Examiner  
Art Unit 3761

KMR  
January 29, 2007